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Alfieri

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(54) **HAND ACCESS DEVICE**

(56) **References Cited**

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U.S. PATENT DOCUMENTS

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3,402,710	A	9/1968	Paleschuck
4,016,884	A	4/1977	Kwan-Gett
4,183,357	A	1/1980	Bentley et al.
4,402,683	A	9/1983	Kopman
4,863,438	A	9/1989	Gauderer et al.
5,159,921	A	11/1992	Hoover
5,242,415	A	9/1993	Kantrowitz et al.
5,366,478	A	11/1994	Brinkerhoff et al.
5,375,588	A	12/1994	Yoon
5,391,156	A	2/1995	Hildwein et al.
5,437,683	A	8/1995	Neumann et al.
5,460,170	A	10/1995	Hammerslag
5,480,410	A	1/1996	Cuschieri et al.
5,490,843	A	2/1996	Hildwein et al.
5,514,133	A	5/1996	Golub et al.

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(Continued)

FOREIGN PATENT DOCUMENTS

EP	0538060	A1	4/1993
EP	0950376	A1	10/1999

(Continued)

OTHER PUBLICATIONS

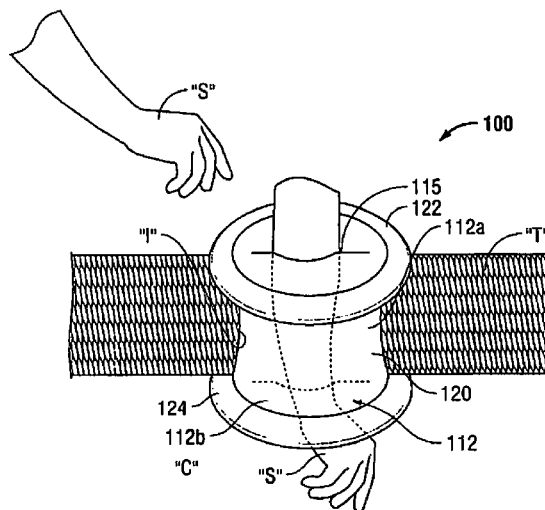
European Search Report for corresponding European Appln. No. EP11194238 mailed Mar. 19, 2012. (4 pgs.).

Primary Examiner — Pedro Philogene

(57) **ABSTRACT**

A device for accessing a body cavity through an opening in tissue is provided. The access device includes a unitary compressible body configured to be received in an opening in tissue. The compressible body includes a central portion, an upper rim located on a proximal end of the body and a lower rim located on a distal end of the body. The central portion defines a slit configured to permit the passage of a hand therethrough in a sealing manner.

6 Claims, 3 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

5,522,791	A	6/1996	Leyva	7,815,567	B2	10/2010	Albrecht et al.
5,524,644	A	6/1996	Crook	7,837,612	B2	11/2010	Gill et al.
5,545,179	A	8/1996	Williamson, IV	7,867,164	B2	1/2011	Butler et al.
5,556,385	A	9/1996	Andersen	7,909,760	B2	3/2011	Albrecht et al.
5,634,937	A	6/1997	Mollenauer et al.	7,951,076	B2	5/2011	Hart et al.
5,649,550	A	7/1997	Crook	7,998,068	B2	8/2011	Bonadio et al.
5,653,705	A	8/1997	de la Torre et al.	2001/0037053	A1	11/2001	Bonadio et al.
5,672,168	A	9/1997	de la Torre et al.	2003/0014076	A1	1/2003	Mollenauer et al.
5,728,103	A	3/1998	Picha et al.	2004/0015185	A1	1/2004	Ewers
5,741,298	A	4/1998	MacLeod	2004/0092795	A1	5/2004	Bonadio et al.
5,803,921	A	9/1998	Bonadio	2004/0111061	A1	6/2004	Curran
5,813,409	A	9/1998	Leahy et al.	2004/0127772	A1*	7/2004	Ewers A61B 1/06 600/212
5,830,191	A	11/1998	Hildwein et al.	2004/0267096	A1	12/2004	Caldwell et al.
5,906,577	A	5/1999	Beane et al.	2005/0020884	A1	1/2005	Hart et al.
5,916,198	A	6/1999	Dillow	2005/0096695	A1	5/2005	Olich
5,941,898	A	8/1999	Moenning et al.	2005/0148823	A1	7/2005	Vaugh et al.
5,951,588	A	9/1999	Moenning	2005/0192483	A1	9/2005	Bonadio et al.
5,957,913	A	9/1999	de la Torre et al.	2006/0071432	A1	4/2006	Staudner
5,964,781	A	10/1999	Mollenauer et al.	2006/0149137	A1	7/2006	Pingleton et al.
6,017,355	A	1/2000	Hessel et al.	2006/0149306	A1	7/2006	Hart et al.
6,018,094	A	1/2000	Fox	2006/0161049	A1	7/2006	Beane et al.
6,024,736	A	2/2000	de la Torre et al.	2006/0161050	A1	7/2006	Butler et al.
6,033,426	A	3/2000	Kaji	2006/0241651	A1	10/2006	Wilk
6,033,428	A	3/2000	Sardella	2006/0247500	A1	11/2006	Voegelé et al.
6,077,288	A	6/2000	Shimomura et al.	2006/0247516	A1	11/2006	Hess et al.
6,110,154	A	8/2000	Shimomura et al.	2006/0247586	A1	11/2006	Voegelé et al.
6,142,936	A	11/2000	Beane et al.	2006/0247678	A1	11/2006	Weisenburgh et al.
6,241,768	B1	6/2001	Agarwal et al.	2006/0270911	A1	11/2006	Voegelé et al.
6,254,534	B1	7/2001	Butler et al.	2007/0118175	A1	5/2007	Butler et al.
6,315,770	B1	11/2001	de la Torre et al.	2007/0151566	A1	7/2007	Kahle et al.
6,319,246	B1	11/2001	de la Torre et al.	2007/0203398	A1	8/2007	Bonadio et al.
6,382,211	B1	5/2002	Crook	2007/0208312	A1	9/2007	Norton et al.
6,440,063	B1	8/2002	Beane et al.	2007/0270654	A1	11/2007	Pignato et al.
6,450,983	B1	9/2002	Rambo	2007/0270882	A1	11/2007	Hjelle et al.
6,454,783	B1	9/2002	Piskun	2008/0027476	A1	1/2008	Piskun
6,578,577	B2	6/2003	Bonadio et al.	2008/0097162	A1	4/2008	Bonadio et al.
6,582,364	B2	6/2003	Butler et al.	2008/0200767	A1	8/2008	Ewers et al.
6,589,167	B1	7/2003	Shimomura et al.	2009/0012477	A1	1/2009	Norton
6,613,952	B2	9/2003	Rambo	2009/0036745	A1	2/2009	Bonadio et al.
6,623,426	B2	9/2003	Bonadio et al.	2009/0093752	A1*	4/2009	Richard A61B 17/3423 604/24
6,814,078	B2	11/2004	Crook	2009/0093850	A1	4/2009	Richard
6,840,951	B2	1/2005	de la Torre et al.	2009/0137879	A1	5/2009	Ewers et al.
6,846,287	B2	1/2005	Bonadio et al.	2009/0187079	A1*	7/2009	Albrecht et al. 600/206
6,916,310	B2	7/2005	Sommerich	2009/0204067	A1	8/2009	Abu-Halawa
6,916,331	B2	7/2005	Mollenauer et al.	2009/0221968	A1	9/2009	Morrison et al.
6,939,296	B2	9/2005	Ewers et al.	2009/0326332	A1	12/2009	Carter
6,945,932	B1	9/2005	Caldwell et al.	2010/0063452	A1	3/2010	Edelman et al.
6,958,037	B2	10/2005	Ewers et al.	2010/0100043	A1	4/2010	Racenet
6,972,026	B1	12/2005	Caldwell et al.	2010/0240960	A1	9/2010	Richard
7,008,377	B2	3/2006	Beane et al.	2010/0249523	A1	9/2010	Spiegel et al.
7,033,319	B2	4/2006	Pulford et al.	2010/0249524	A1	9/2010	Ransden et al.
7,052,454	B2	5/2006	Taylor	2010/0286484	A1	11/2010	Stellon et al.
7,101,353	B2	9/2006	Lui et al.	2010/0298646	A1	11/2010	Stellon et al.
7,153,261	B2	12/2006	Wenchell	2011/0009704	A1	1/2011	Marczyk et al.
7,163,510	B2	1/2007	Kahle et al.	2011/0021877	A1	1/2011	Fortier et al.
7,195,590	B2	3/2007	Butler et al.	2011/0028891	A1	2/2011	Okoniewski
7,214,185	B1	5/2007	Rosney et al.	2011/0034778	A1	2/2011	Kleyman
7,238,154	B2	7/2007	Ewers et al.	2011/0054257	A1	3/2011	Stopek
7,300,399	B2	11/2007	Bonadio et al.	2011/0054258	A1	3/2011	O'Keefe et al.
7,331,940	B2	2/2008	Sommerich	2011/0082341	A1	4/2011	Kleyman et al.
7,344,547	B2	3/2008	Piskun	2011/0082343	A1	4/2011	Okoniewski
7,377,898	B2	5/2008	Ewers et al.	2011/0082346	A1	4/2011	Stopek
7,393,322	B2	7/2008	Wenchell	2011/0313250	A1*	12/2011	Kleyman 600/123
7,445,597	B2	11/2008	Butler et al.	2012/0095297	A1*	4/2012	Dang A61B 17/0218 600/208
7,473,221	B2*	1/2009	Ewers et al. 600/208	FOREIGN PATENT DOCUMENTS			
7,481,765	B2*	1/2009	Ewers et al. 600/208	EP	1312318	A1	5/2003
7,540,839	B2	6/2009	Butler et al.	EP	2044889	A1	4/2009
7,559,893	B2	7/2009	Bonadio et al.	EP	2095781	A2	9/2009
7,608,082	B2	10/2009	Cuevas et al.	EP	2098182	A2	9/2009
7,650,887	B2	1/2010	Nguyen et al.	EP	2181657	A2	5/2010
7,704,207	B2	4/2010	Albrecht et al.	EP	2229900	A1	9/2010
7,717,847	B2	5/2010	Smith	EP	2238924	A1	10/2010
7,727,146	B2	6/2010	Albrecht et al.	EP	2238925	A1	10/2010
7,736,306	B2	6/2010	Brustad et al.	EP	2248478	A1	11/2010
7,766,824	B2	8/2010	Jensen et al.				

(56)

References Cited

FOREIGN PATENT DOCUMENTS

EP	2253283	A1	11/2010
EP	2272450	A2	1/2011
EP	2277464	A1	1/2011
EP	2292165	A2	3/2011
WO	WO 96/36283		11/1996
WO	WO 01/08581	A2	2/2001

WO	WO 01/32116	A1	5/2001
WO	WO 01/32120	A1	5/2001
WO	WO 03/034908	A2	5/2003
WO	WO 2004/043275	A1	5/2004
WO	WO 2004/054456	A1	7/2004
WO	WO 2004/075741	A2	9/2004
WO	WO 2006/110733	A2	10/2006
WO	WO 2008/103151	A2	8/2008
WO	WO 2009/036343	A1	3/2009

* cited by examiner

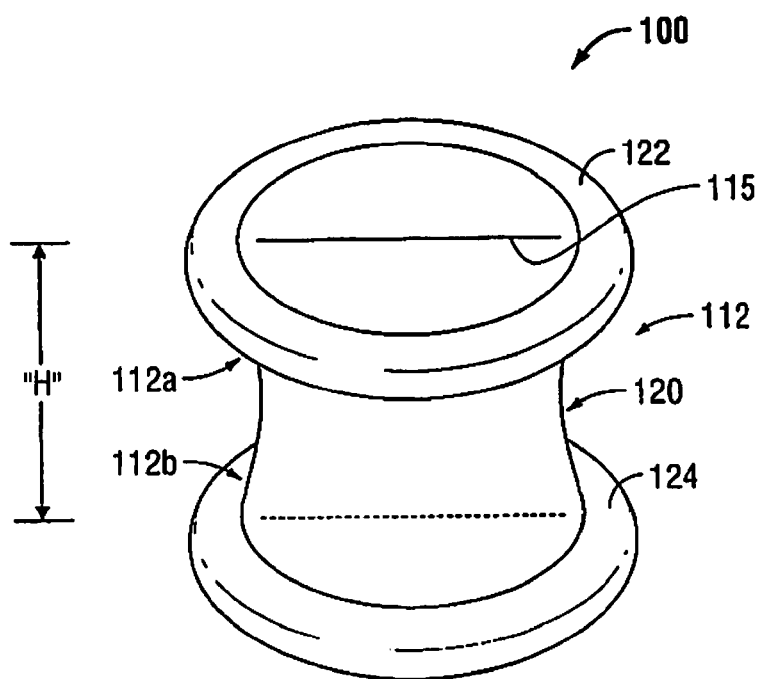


FIG. 1

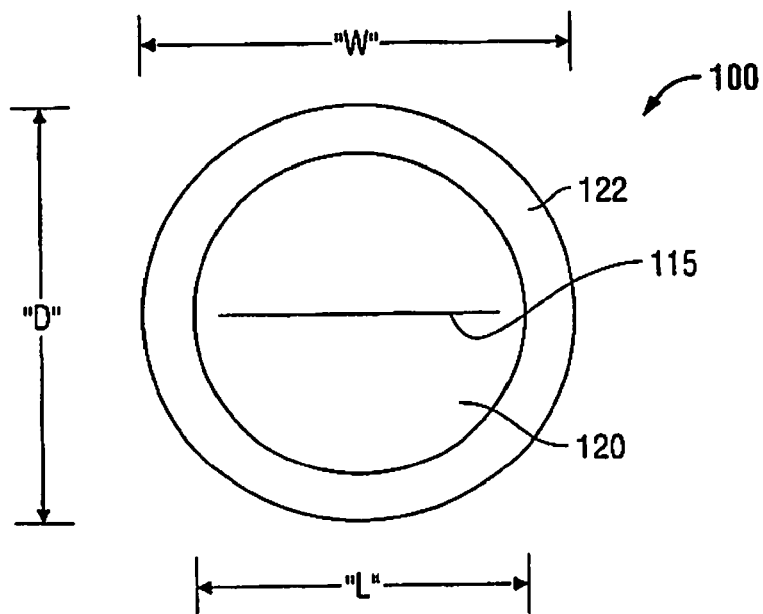


FIG. 2

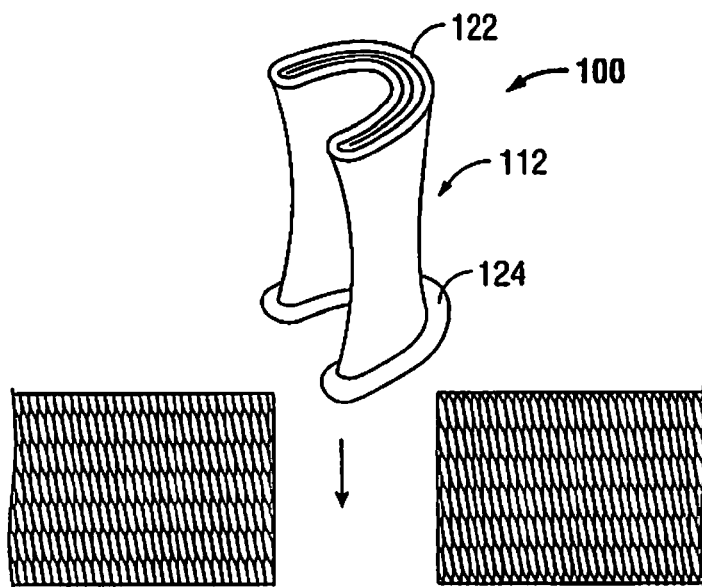


FIG. 3

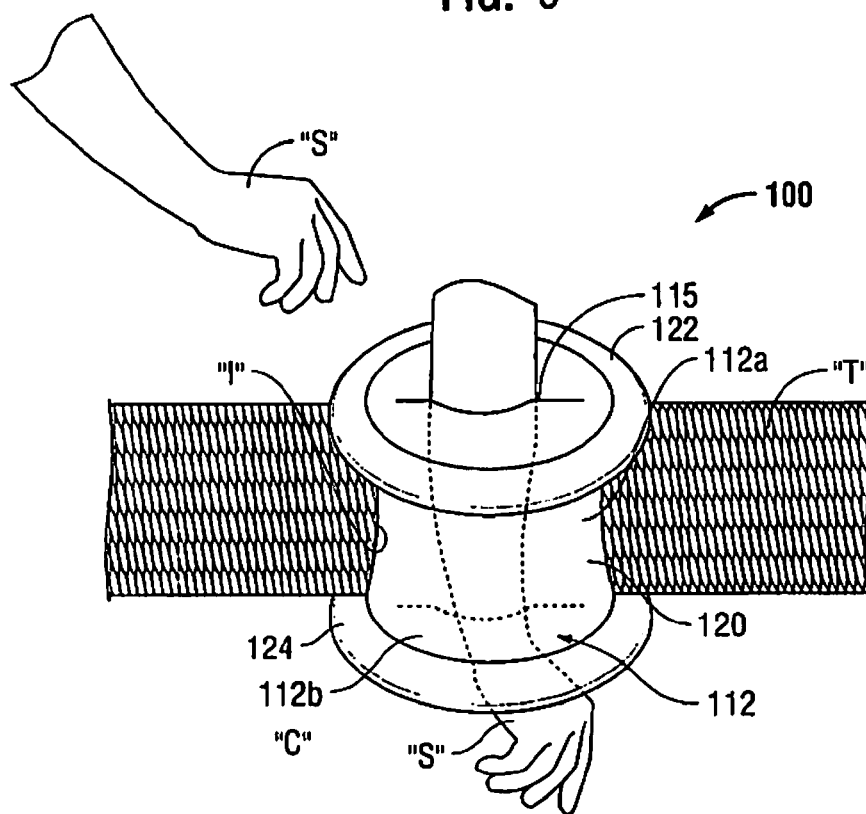


FIG. 4

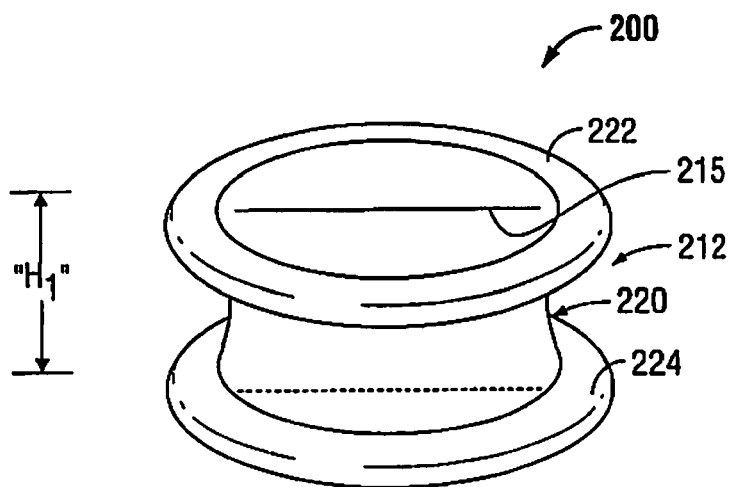


FIG. 5

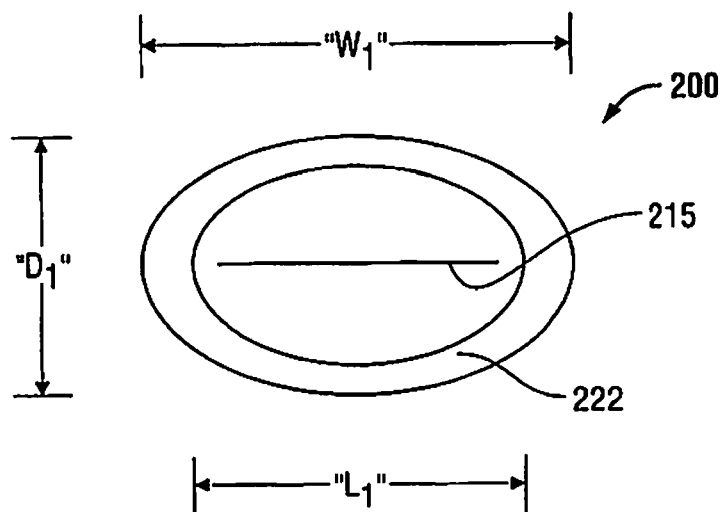


FIG. 6

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HAND ACCESS DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 13/223,659 filed Sep. 1, 2011, which claims benefit of Provisional application No. 61/424,761 filed Dec. 20, 2010, and the disclosures of each of the above-identified applications are hereby incorporated by reference in their entirety.

BACKGROUND

1. Technical Field

The present disclosure relates to access devices for use in surgical procedures. More particularly, the present disclosure relates to compressible access devices configured for sealed receipt of a hand therethrough.

2. Background of Related Art

Access assemblies configured for reception through an opening or incision into a body cavity are known, as are methods of inserting the access assemblies therethrough. Traditional access assemblies include a rigid cannula that is received through the tissue of the body wall into the body cavity. Endoscopic, laparoscopic and other suitable instruments may then be directed through a housing located on the proximal end of the cannula to access the body cavity in a sealing manner.

Compressible devices or assemblies configured for accessing a body cavity and permitting reception of instruments therethrough in a sealing manner are also known. Such compressible assemblies are composed of silicone, thermoplastic elastomers (TPE), rubber, foam, gel and other compressible materials and are configured to be compressed to facilitate insertion into an incision. Typically, such assemblies are deformed by a surgeon using his/her fingers or with the assistance of a grasping device, i.e., forceps. Compression of the assembly reduces the profile of the assembly, thereby facilitating reception of the assembly into the incision. Upon release of the compressive force, the previously compressed assembly returns to an uncompressed configuration. One or more endoscopic or laparoscopic devices may then be inserted through one or more lumens in the assembly to complete a procedure.

Although advances have been made with regards to endoscopic and laparoscopic instrumentation, there is still no comparison to the dexterity and feel of one's hand. Being able to access a surgical site with a hand enables a surgeon to perform procedures that he/she would not otherwise be able to perform during a closed procedure. Thus, any procedure performed with hand access more closely resembles an open procedure, which a surgeon may be more comfortable performing.

Therefore, it would be beneficial to have a compressible access device which provides hand access for a surgeon.

SUMMARY

The present invention, in accordance with an embodiment thereof, relates to an access device comprising a unitary, compressible body configured to be received in an opening in tissue, the compressible body including a central portion, an upper rim located on a proximal end of the body and a lower rim located on a distal end of the body, wherein the central portion defines a slit configured to permit the passage of a hand therethrough in a sealing manner. The compressible body may define a substantially hour-glass shape. The

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upper and lower rims and the central portion may be substantially circular or substantially oval. The upper and lower rims may be substantially similar. The opening in the tissue may be an incision or a natural orifice. Each of the upper and lower rims may include a width of four inches (4") and a depth of four inches (4"). Alternatively, each of the upper and lower rims may include a width of four inches (5") and a depth of four inches (3"). The slit may include a length of at least two and one-half inches (2.5"). The compressible body may be composed of silicone, thermoplastic elastomers (TPE), rubber, foam and/or gel.

DESCRIPTION OF THE DRAWINGS

Embodiments of a compressible access device are disclosed herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of an embodiment of an access device according to the present disclosure;

FIG. 2 is a top view of the access device of FIG. 1;

FIG. 3 is a perspective view of the access device of FIGS. 1 and 2, in a compressed condition prior to insertion through an incision;

FIG. 4 is a perspective view of the access device of FIGS. 1-3, selectively secured within an incision;

FIG. 5 is a perspective view of an access device according to an alternative embodiment of the present disclosure; and
FIG. 6 is a top view of the access device of FIG. 5.

DETAILED DESCRIPTION

Embodiments of the presently disclosed access device will now be described in detail with reference to the drawings wherein like numerals designate identical or corresponding elements in each of the several views. As is common in the art, the term "proximal" refers to that part or component closer to the user or operator, i.e. surgeon or physician, while the term "distal" refers to that part or component further away from the user. Although the access devices of the present disclosure will be described as relates to accessing an abdominal cavity through an incision in the abdominal wall, the access devices of the present disclosure may be modified for use in other closed procedures, i.e., laparoscopic, arthroscopic, endoscopic. Furthermore, the access devices of the present disclosure may be modified for use in accessing internal cavities through natural orifices, e.g., anus, vagina.

Referring initially to FIG. 1, an access device according to an embodiment of the present disclosure is shown generally as access device 100. Access device 100 is configured for insertion through an opening in tissue, i.e., an incision, such that after insertion, access device 100 creates a seal within the opening through which a surgeon may insert and manipulate his/her hand "H" (FIG. 4) and/or one or more surgical instruments (not shown) to complete a procedure.

With reference to FIGS. 1 and 2, access device 100 includes a substantially compressible and/or flexible body 112. Body 112 may be formed of various materials, such as, for example, silicone, thermoplastic elastomers (TPE), rubber, foam, gel, etc. In one embodiment, body 112 includes a TPE material that is infused with an inert gas, e.g. CO₂ or Nitrogen, to form a foam structure. Body 112 may be coated with a lubricant, e.g. Parylene N or C, in order to create a lubricious outer surface. Various other coatings, e.g., hydrophilic, hydrophobic, bio-agents, anti-infection, analgesic, may also be employed to improve the characteristics of access device 100 or to adapt access device 100 for a specific procedure.

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With reference still to FIGS. 1 and 2, body 112 includes a substantially cylindrical central portion 120, an upper rim 122 located on a proximal end 112a, and a lower rim 124 located at a distal end 112b. In this manner, body 112 defines a substantially hourglass shape when viewed from the side. Upper and lower rims 122, 124 are integrally formed with central portion 120 and define substantially annular members. Central portion 120 is configured to span the thickness of tissue "T". Upper and lower rims 122, 124 aid in preventing movement of access device 100 longitudinally through incision "I" once access device 100 has been properly received therethrough. As the thickness of tissue depends on the body composition of the patient and the location through which the underlying cavity is being accessed, the length and size of access device 100, generally, and central portion 120, specifically, may be modified to suit a given procedure. In this manner, an adult patient having fatty abdominal tissue requires an access device having a longer central portion 112 than an access assembly sized for an child.

Still referring to FIGS. 1 and 2, body 112 defines a slit 115 extending longitudinally therethrough. Slit 115 extends the length of body 112 and provides a resealable opening through which a hand "H" of a surgeon may be passed. As shown, slit 115 spans substantially the width of central portion 120. Body 112 is configured such that hand "H" may be passed through slit 115 of access device 100 while maintaining an insufflation gas within a body cavity "C". In this manner, body 112 of access device 100 forms a seal about the hand and lower arm of the surgeon, to permit sealed passage of hand "H" therethrough. Body 112 may include a coating about slit 115 to prevent tearing and/or to facilitate reception of hand "H" therethrough.

With reference still to FIGS. 1 and 2, body 112 of access assembly 100 defines a substantially hourglass shape having a height "H". Upper and lower rims 122, 124 each define substantially circular members having a width "W" and a depth "D". As shown, each of upper and lower rims 122, 124 have similar sizes and shapes, however, it is envisioned that rims 122, 124 may differ in size and/or shape. Slit 115 defines a planar opening spanning a length "L" of central portion 120. The size of access device 100 is needed to be large enough to permit passage of hand "H" through slit 115 without tearing of body 112, however, access device 100 should not be so large as to create an unnecessarily large opening in tissue "T" of the patient that may be difficult to close and/or may leave a decidedly large scar. As the size of a hand "H" differs from surgeon to surgeon, access device 100 may be provided in various sizes to accommodate the surgeon. In one embodiment, width "W" and depth "D" of first and second rims 122, 124 and height "H" of body 112 each measure between three inches (3") and five inches (5"), and preferably, four inches (4"). In the same embodiment, slit 115 includes a length "L" of at least two and one-half inches (2.5").

The use of access device 100 will now be described with reference to FIGS. 3 and 4. The following discussion will include the use of access device 100 for accessing a body cavity "C" through an incision "I" in tissue "T". As discussed above, access device 100 may be used for accessing various cavities or lumen through other openings, including naturally occurring orifices, e.g., anus.

Referring initially to FIG. 3, an incision "I" is created in tissue "T" through which access device 100 is to be inserted to access body cavity "C". Body 112 of access device is then compressed to reduce the profile of access device 100. This may be accomplished by hand or instead, through the use of

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an insertion mechanism (not shown). By reducing the profile of access device 100, access device 100 may be more easily inserted through incision "I".

Turning to FIG. 4, once received through incision "I", body 112 of access device 100 is permitted to return to an initial, uncompressed condition. Decompression of access device 100 causes access device 100 to expand within incision "I", thereby effectively sealing body cavity "C". Once sealed, body cavity "C" may be insufflated and access device 100 operates in a manner similar to traditional access assemblies configured for use with surgical instruments.

Removal of access assembly 100 from within incision "I" occurs in the reverse order of insertion. Body 112 is once again compressed to reduce the profile of access device 100. Once compressed, access device 100 may be readily withdrawn from incision "I". Once access assembly 100 is removed from incision "I", incision "I" is closed in a conventional manner, i.e., sutures, staples.

Turning now to FIGS. 5 and 6, an access device according to an alternative embodiment of the present disclosure is shown generally as access device 200. Access device 200 is substantially similar to access device 100 described hereinabove, and will only be described as relates to the differences therebetween. Access device 200 includes a body 212 having a central portion 220, an upper rim 222 located on a proximal end thereof and a lower rim 224 located on a distal end thereof. Body 212 defines a slit 215 extending longitudinally through central portion 220. Each of upper and lower rims 222, 224 and central portion 220 define substantially oval members. The oval shape of upper and lower rims 222, 224 and central portion 220 permits a longer slit 215. In this manner, access device 200 is configured to more readily accommodate passage of hand "H". Upper and lower rims 222, 224 have a width "W₁" and a depth "D₁". Body 212 includes a height "H₁" and slit 215 includes a length "L₁". In one embodiment, upper and lower rims 222, 224 include a width "W₁" of about five inches (5") and a depth "D₁" of about three inches (3"), body 212 includes a height "H₁" of about three and one-half inches (3.5") and slit 215 includes a length "L₁" of about three inches (3").

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, either or both of the upper and lower rims and the central portion may include selectively inflatable cavities configured to facilitate insertion and removal of the access device through an incision. Therefore, the above description should not be construed as limiting, but merely as exemplifications of particular embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

The invention claimed is:

1. An access device for insertion through an opening in tissue, the access device comprising:

a body formed of a foam material, the body having:
a central portion with a proximal end and a distal end;
an upper rim located on the proximal end of the central portion; and
a lower rim located on the distal end of the central portion,

at least one of the upper rim or the lower rim having an oval cross-section relative to a longitudinal axis of the body when the body is in an at-rest state, the at least one of the upper rim or the lower rim defining a major axis and a minor axis, the body transitionable between a compressed condition adapted to facilitate insertion thereof through the opening in the tissue and an uncompressed condition adapted to secure the

body within the opening in the tissue in a sealing relation, the at least one of the upper rim or the lower rim defining a slit between the upper and lower rims of the body, wherein the slit extends a substantial length of the at least one of the upper rim or the lower rim along the major axis, the slit extending between proximal and distal ends of the body. 5

2. The access device according to claim 1, wherein the central portion includes an oval cross-section.

3. The access device according to claim 1, wherein the body defines an hourglass shape. 10

4. The access device according to claim 1, wherein the upper and lower rims are integrally formed with the central portion.

5. The access device according to claim 2, wherein the central portion has the oval cross-section when the body is in the at-rest state. 15

6. The access device according to claim 1, wherein the oval cross-section of the at least one of the upper rim or the lower rim is transverse to the longitudinal axis of the body. 20

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